

Overview of Data Access and Privacy Policies Relevant to the Environmental Public Health Tracking Network

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Purpose & Overview

- Provide a broad overview of data privacy and confidentiality policies at different levels of U.S. government
 - ▶ Federal
 - FOIA
 - Privacy Act
 - The “Common Rule”
 - FERPA
 - HIPAA & Privacy Rule
 - CIPSEA
 - ▶ State trends

A Balancing Act



Legal and ethical
rights to privacy

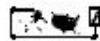
vs.

Need to inform
public health decisions

Methodology

- Literature
 - ▶ Published reports, journal articles, official documents, websites, databases;
 - ▶ CDC tracking grantees information, including March 05 reports describing tracking legislation
 - ▶ Implementation plan site interviews (by R&A)
- Telephone interviews
 - ▶ CDC and health agencies in CA, FL, ME, MN, MO, MN, MT, OK, WA; and the City of Houston;
 - ▶ The Center for Law and the Public's Health
 - ▶ The National Council of State Legislators
- Informal inquiries:
 - ▶ ASTHO, NACCHO, NBDPN, NCI

Two Key References



Council of State and
Territorial Epidemiologists



CDC-CSTE Intergovernmental Data Release Guidelines
Working Group (DRGWG) Report:

CDC-ATSDR Data Release Guidelines and Procedures
for Re-release of State-Provided Data

*This report contains guidelines for implementing the CDC/ATSDR Policy on Releasing
and Sharing Data, pertaining to the re-release of State-provided data.*

L:\WPWD\DCSDR\Gdrgwg report ver 12.doc

<http://www.cste.org/pdffiles/2005/drgwgreport.pdf>

1 of 86



MMWR

Morbidity and Mortality Weekly Report

Early Release

April 11, 2003 / Vol. 52

HIPAA Privacy Rule and Public Health

Guidance from CDC and the U.S. Department
of Health and Human Services

<http://www.cdc.gov/privacyrule/Guidance/PRmmwrguidance.pdf>

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION

Freedom of Information Act of 1966 (FOIA)

- Requires federal agencies to release any records that are not already in the public domain, (unless covered by one of the 9 exemptions)
- Applies only to federal agencies
- Covers only records in the possession and control of those agencies
- State based data become federal records when in the possession of federal agencies

FOIA Exemptions

- **Trade secrets, commercial information or otherwise ‘privileged and confidential’**
 - ▶ Commercial = related to businesses, financial info
 - ▶ Privileged = legal sense e.g. attorney client privilege
 - ▶ Confidential =
 - Impairs government ability to obtain information
 - Harms competitive position
 - Impairs government interest
 - Impairs other private interests
- Internal personnel rules and practices
- Personnel or medical files and similar files that would constitute a clearly unwarranted invasion of personal privacy
- Interagency memo not available by law (predecisional)
- Law enforcement
- National Security
- Supervision of financial institutions
- Geological and geophysical information
- Prohibited by other laws

Privacy Act of 1974

- Early attempt to regulate the collection, maintenance, use, and dissemination of personal information by federal executive branch agencies
- Key tenet: No disclosure without consent
- Imprecise language, difficult to decipher

The Common Rule

(protection of human subjects)

- HHS Regulation (adopted by Executive Branch Agencies/Depts)
- Three basic tenets of human subjects research:
 - ▶ **Institutional assurance of compliance:** any institution engaged in human subjects research commits in writing to the protection of those subjects.
 - ▶ **Institutional Review Board (IRB):** formal committee that reviews research activities commonly conducted by the institution.
 - ▶ **Informed Consent:** voluntary choice of individuals to participate in research based on an accurate understanding of its purposes, procedures, risks, benefits, alternatives, and any other factors that may affect a person's decision to participate.
- Not generally applicable to Tracking because tracking is surveillance not research.

Chart 1: Is an Activity Research Involving Human Subjects Covered by 45 CFR part 46?

September 24, 2004

Start here.

Is the activity a **systematic** investigation **designed** to develop or contribute to **generalizable** knowledge? [45 CFR 46.102(d)]

NO → Activity is not research, so 45 CFR part 46 does not apply.

YES → Activity is research. Does the research involve **obtaining information about living individuals**? [45 CFR 46.102(f)]

NO → The research is not research involving human subjects, and 45 CFR part 46 does not apply.

YES → Does the research involve **intervention or interaction** with the individuals? [45 CFR 46.102(f)(1), (2)]

NO → Is the information **individually identifiable** (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information)? [45 CFR 46.102(f)(2)]

YES → Is the information **private**? (About)

YES → Activity is research involving human subjects. Is it **conducted or**

NO → BUT

<http://www.hhs.gov/ohrp/human>

Confidentiality Protections in the Public Health Service Act

- Public Health Service (PHS) Act of 1944 Part A 42 [USC § 241(d), 242(m)(d), 308(d)m and 301(d)] covers research activities in the public health service
- Certificates of Confidentiality are issued by the National Institutes of Health (NIH) to protect identifiable research information from forced disclosure
 - ▶ Additional assurance against FOIA requests
- Data collected under a project with a 308(d) assurance of confidentiality may not be released in identifiable form without the consent of the individual or entity that supplied the information

HIPAA & the Privacy Rule

- Health Insurance Portability and Accountability Act of 1996 [45 CFR § 160 and 164]
- First national standard for protecting the privacy of health care
- In general, public health uses are exempt from the privacy rule
- Applies to all “protected health information” – electronic, paper, oral – held or transmitted by a covered entity



Definitions

- **Protected Health Information (PHI)** – Health information that can be linked to an individual through common identifiers (e.g., name, address, birth date, Social Security number)
- **Individually Identifiable** – Data or information that can be used to establish individual identity

Provisions of the Privacy Rule

- **Limits use and disclosure of individually identifiable health information**
- Gives patients the right to access medical records
- Limits release of information to 'minimum reasonably needed'
- Requires covered entities provide a notice of privacy practices
- Establishes safeguards and restrictions regarding the use and disclosure of records for surveillance and research

Who Must Comply?

- “Covered” entities include
 - ▶ Health plans, insurers, HMOs, Medicaid, Medicare and Veterans Health Authority
 - ▶ Health care clearing houses, such as billing services, re-pricing companies or community health information systems
 - ▶ All other providers who deliver or bill for services
- CDC and other Public Health Authorities funded to conduct public health activities are not covered entities.
 - ▶ In fact, PHAs may be required by law to collect individually identifiable information
 - ▶ CDC can transfer Public Health Authority to others (e.g., EPA)

De-identifying Data

- Individually identifiable information can be removed to create:
 - ▶ Limited Data Set
 - Contains some identifying information such as geographic location, dates of treatment, other codes or identifiers
 - Special data sharing agreement required for use
 - ▶ Public Use Data Set (PUDS)
 - May be used by anyone, without restriction
 - Does not contain any identifiers, name, address, photographs, medical ID, SSN, etc

Protected Health Information (Identifiers Prohibited from PUDS)

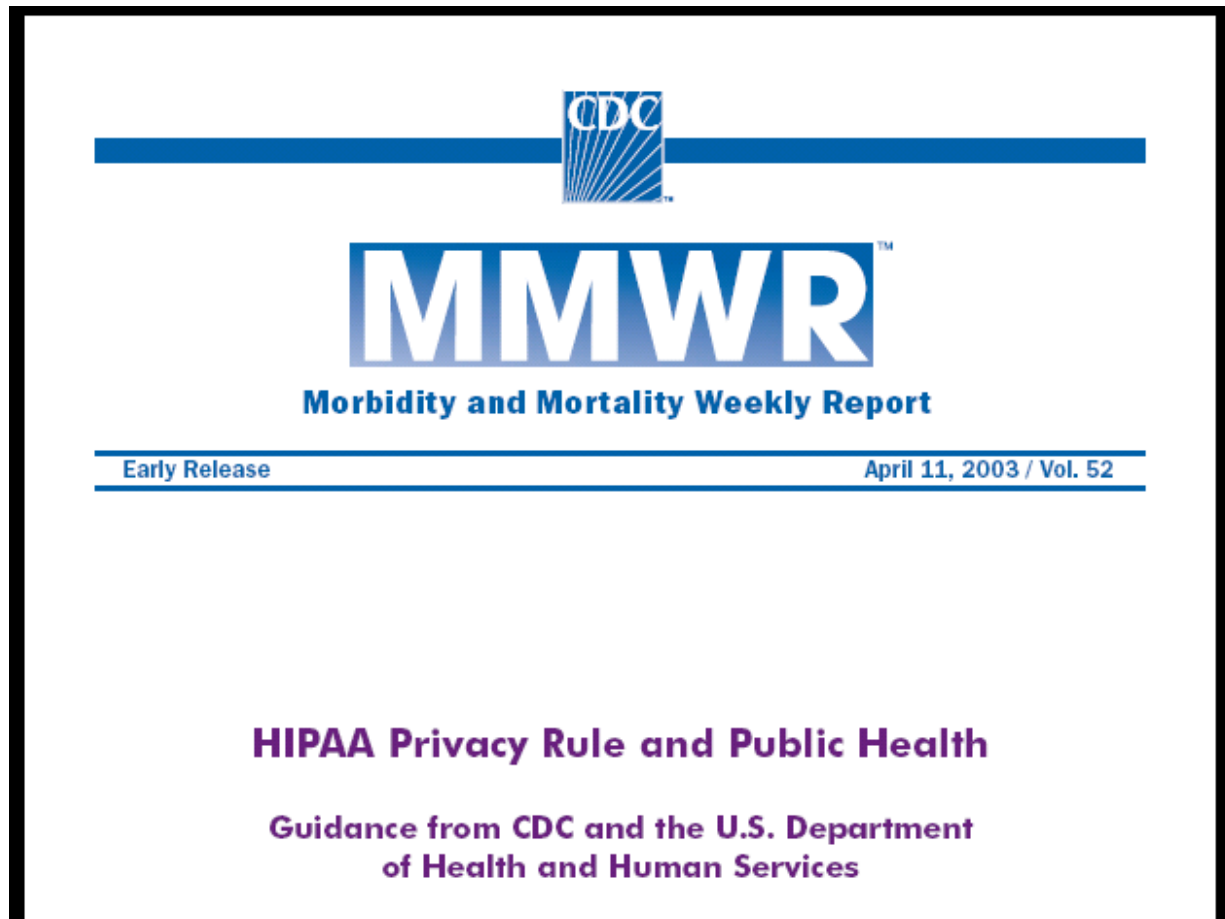
- Name
- Geographic identifier more specific than state (first 3 digits of zip OK if pop > 20,000)
- Date information related to an individual (birth, death, treatment)
- Phone, fax numbers, email
- SSN
- Medical Record #
- Health plan #
- Account number
- Certificate/license numbers
- Vehicle ID numbers
- Device ID and serial #
- IP address
- Biometric identifier finger and voice print
- Photographs
- Other unique identifier

PHI and Public Health

- Protected health information may be used for public health activities (e.g., surveillance) and research
 - ▶ [45 CFR § 164 512(b)]

CDC Guidance

<http://www.cdc.gov/privacyrule/Guidance/PRmmwrguidance.pdf>



Privacy Rule and Research

- Covered entities may share PHI with researchers, but should be carefully reviewed
- PHI may be disclosed when
 - ▶ Patients give consent
 - ▶ Proposals
 - ▶ Deceased persons
 - ▶ Limited use datasets covered by a data sharing agreement
- The Privacy Rule does not apply to all investigations
 - ▶ E.g., when information is collected for purposes ‘other than general knowledge collection’ (such as for evaluation)

Family Educational Rights and Privacy Act of 1974 (FERPA)

- Protects privacy of student education records
- Applies to all schools that receive funds from US Dept of Education
- Written authorization from parent or student required before student records can be released
- Use (surveillance v research) not a distinguishing factor
- Exceptions
 - ▶ School officials, transfer, audit/evaluation, financial aid, studies for the school, accreditation, judicial order or subpoena, health and safety emergencies, juvenile justice

Confidentiality Information Protection and Statistical Efficiency Act of 2002 (CIPSEA)

- New confidentiality protections for statistical data and information
- Authorizes sharing of “business data” among Bureaus of Census, Economic Analysis and Labor Statistics
- Data sharing agreements must be established
- Information must be published in a form that does not breach confidentiality of organizations or names

Disease and Hazard Specific

- Generally covered by state laws and regulations
- Cancer
 - ▶ Public Health Services Act establishes the National Program for Cancer Registries
 - ▶ States must ensure confidentiality of case data to receive federal funds
- Lead
 - ▶ Lead-Based Paint Disclosure Rule - HUD and EPA required to disclose information prior to home sales
 - ▶ Lead Contamination Control Act – established CDC Childhood Lead Poisoning Prevention Branch

State Trends: Laws and Regulations



A Few Generalities

- State privacy & confidentiality policies are diverse, though every state protects personal health data held by government agencies
- Policies rarely specify criteria for who may have access
- Policies are generally silent on secondary uses of information
- 49 states allow disclosure for public health purposes (statistical evaluation (N=43) or epidemiological investigations (N=22))

From Gostin et al. (1996) http://www.epic.org/privacy/medical/cdc_survey.html

Categories of State Laws & Regulations

- Disease Specific
 - ▶ Cancer Registries
 - ▶ Lead Poisoning
 - ▶ Birth Defects
 - ▶ Asthma
- Reportable Diseases
- Emergency Health Powers Acts
- Tracking Specific Laws

Cancer Registries

- 45 states have authorized cancer registries via legislative acts
- National Program for Cancer Registries (NPCR) established in 1992 to fund state cancer registry programs
 - ▶ Funding requires state regulations to address data access, confidentiality, and disclosure
- North American Association for Central Cancer Registries (NAACCR)
 - ▶ “Certification” requires certain standards for confidentiality and disclosure

Lead Poisoning

- Many states have regulations pertaining to blood-lead levels
- Provide confidentiality protections
- Allow public health agency access for surveillance and intervention

Birth Defects

- 41 States and Puerto Rico have authorized birth defects surveillance
- Legislative approaches are varied
- NBDPN published a table of state BD legislation

<http://www.nbdpn.org/current/resources/sgm/a>

Table of State Birth Defects Legislation

State Birth Defects Legislation – April 2004				
State	Name of Birth Defects Surveillance Program	Leg/Rule	Year	Citation
Alabama	Alabama Birth Defects Surveillance and Prevention Program	Yes	2001	Code of Ala. § 22-10A-2
Alaska	Alaska Birth Defects Registry (ABDR)	Yes	1996 (enact)	7AAC 27.012
Arizona	Arizona Birth Defects Monitoring Program	Yes	1988 (enacted); 1991 (adopted); 2001 (revised)	Statute: ARS § 36-133 Rule: Title 9, Chapter 4, Articles 1 & 5 A.R.S. § 36-133 (2001)
Arkansas	Arkansas Reproductive Health Monitoring System	Yes	1985 (enacted); 1999 (revised)	Bill 214 (1985) A.C.A. § 20-16-201
California	California Birth Defects Monitoring Program	Yes	1982 (enacted); 1996 (recodified)	Health and Safety Code, Division 102, Part 2, Chapter 1, Sections 103825-103855, effective 1982. Recodified 1996: § 103825, 103855, 103830, 103835, 125050, 103840, 103850, 125000
Colorado	Colorado Responds To Children With Special Needs	Yes	1985 (enacted)	Colorado Revised Statutes 25-1.5-101 - 25-1.5-105
Connecticut	Connecticut Birth Defects Registry	Yes	1991 (enacted)	Sec. 10a-132b transferred to sec 19a-56a in 1999 § 19a-56a, 19a-56b (2001) State has 2 statutes which mandate the reporting of children with birth defects. They are: Sec. 19a-53. (Formerly Sec. 19-21). Reports of physical defects of children; Sec. 19a-54. (Formerly Sec. 19-21a).

Notifiable/Reportable Diseases

- No federal law requires states to report disease incidence to CDC
- Reportable disease laws reside in states, and thus vary significantly
- CDC and CSTE have cooperated to define a list of “Nationally Reportable Diseases” that CDC tracks
 - ▶ 79 diseases
- States submit data to CDC via the National Electronic Telecommunications System for Surveillance (NETSS)
- Personal identifiers are not submitted to CDC
- CDC has issued guidance to maintain confidentiality by suppressing information if the number of cases is small

State Emergency Health Powers Acts

- Center for Law and the Public's Health (Georgetown) developed a Model Public Health Act (2003)
- Includes emergency powers provision
 - ▶ allows data access and sharing that otherwise would not be legal
- 37 Acts/resolutions directly related to the MPHA have been passed – but no clear pattern of approach to confidentiality has emerged

New Environmental Public Health Tracking Laws

- 14 states have enacted tracking legislation
 - 7 states have pending legislation
 - Can't generalize how these laws address confidentiality issues – some mention it; others do not
-
- Source: National Council of State Legislators database

Take Home Messages”

1. Data privacy and confidentiality policies differ

- ▶ by subject,
- ▶ by situation, and
- ▶ by within and across levels of government

2. For many tracking applications, individually identifiable data can be legally shared and used by public health agencies in accordance with federal laws and regulations

- ▶ Intended USE of the information is often the deciding factor

More “Take Home” Messages

- 3. State laws and regulations differ substantially. Use of state-based data for tracking will need to be assessed against relevant state laws and regulations.**
- 4. Factors other than data privacy and confidentiality policies pose barriers to tracking**
 - ▶ General desire to be protective
 - ▶ Lack of trusted relationships
 - ▶ Red tape
 - ▶ Cost of data acquisition

Related Activity

- National Health Information Security and Privacy Collaboration
- HHS National Coordinator for Health Information Technology, Research Triangle Institute and National Governor's Association
- Funding up to 40 state projects to assess privacy and security laws and business practices that affect the exchange of electronic health information
 - ▶ 34 States involved as of Aug 2, 2006
- <http://www.rti.org/hispc>

Questions?

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